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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/730,663	12/06/2000	Michael J. Hageman	01-677	8091

7590

02/12/2002

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EXAMINER

SHAMEEM, GOLAM M

ART UNIT

PAPER NUMBER

1626

DATE MAILED: 02/12/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

09/730,663

Applicant(s)

HAGEMAN ET AL.

Examiner

Golam M. M. Shameem

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 21 August 2001.
- 2a) ☐ This action is **FINAL**.      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-35 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 1-35 are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

### Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some \* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).  
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

### Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)      4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)      5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_      6) ☐ Other:

## **DETAILED ACTION**

### ***Election/Restrictions***

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claim 1 and 15, drawn to a compound and composition of celecoxib, classified in 548 and 514 classes with plethora of subclasses.
- II. Claims 2-4 and 16, drawn to a celecoxib drug substance and composition, classified in 548 and 514 class with several subclasses.
- III. Claims 5-9 and 17, drawn to a celecoxib crystallization inhibitor composition, classified in 548 and 514 class with several subclasses.
- IV. Claims 10-14 and 18, drawn to a celecoxib crystallization inhibitor composition, classified in 548 and 514 class with several subclasses.
- V. Claim 19, drawn to a process for preparing a celecoxib drug substance classified in 548 and 514 class with several subclasses.
- VI. Claims 20-22, drawn to a process for preparing a celecoxib crystallization inhibitor composition classified in 548 and 514 class with several subclasses.
- VII. Claims 23-25, drawn to a process for preparing a pharmaceutical composition of celecoxib classified in 548 and 514 class with several subclasses.
- VIII. Claims 26-28, drawn to a process for preparing a pharmaceutical composition of celecoxib classified in 548 and 514 class with several subclasses.
- IX. Claims 29-31, drawn to another process for preparing a pharmaceutical composition of celecoxib classified in 548 and 514 class with several subclasses.

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- X. Claims 32-35, drawn to a method of treating a medical condition classified in and 514 class with several subclasses.

The inventions are distinct, each from the other because of the following reasons:

The above groups are identified as general areas. Accordingly, as groups they are independent or distinct as the products (compounds and composition) of groups and would be capable of more than one use. The products of group I-X differ materially so as to be patentably distinct, for example the process of groups VI and VII are distinct because each process has different reactive steps and conditions. Additionally, besides performing a class/subclass search, the examiner performs a commercial data base search and an automated patent system (text) search. Moreover, to not restrict would impose a burden in the examination of this application.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

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A telephone call was made to Mr. Steven Sarussi on 2/1/02 to request an oral election to the above restriction requirement, but did not result in an election being made.

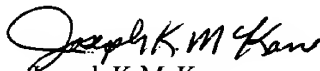
Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Golam Shameem, Ph.D. whose telephone number is 703-305-0116. The examiner can normally be reached on 8:30AM-5:00 PM, M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph McKane can be reached on 703-308-4537. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-7921 for regular communications and 703-308-7921 for after final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1235.

Golam M M Shameem, Ph.D.  
Patent Examiner  
Art Unit 1626, Group 1620  
Technology Center 1

  
Joseph K. McKane  
Supervisory Patent Examiner  
Art Unit 1626, Group 1620  
Technology Center 1

February 7, 2002